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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,388	10/07/2003	John H. Kenten	IGN-2005US03	7445

7590 05/13/2008

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EXAMINER	
HISSONG, BRUCE D	
ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
05/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/681,388	KENTEN ET AL.	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. Applicant's amendment filed on 12/26/2007 has been entered.

2. Applicant's amendments to the claims were sufficient to overcome the rejections under 35 U.S.C. 103(a) (see below). However, upon further consideration, the claim is rejected under 35 U.S.C. 112, first paragraph, as set forth below. Accordingly, the finality of the office action mailed on 9/19/2007 is hereby *withdrawn*, and prosecution on the merits continues.

3. Claim 86 is pending and is the subject of this office action.

Claim Objections

Objection to claim 86, as set forth on page 2 of the office action mailed on 9/19/2007, is *withdrawn* in view of Applicants' amendments to part (a)(iii) of the claim to recite the C-terminus "of the ubiquitin protein".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Rejection of claim 86 under 35 USC § 103(a) as being obvious in view of either Vannier *et al* or Loosfelt *et al*, as set forth on page 6 of the office action mailed on 3/9/2007 and pages 4-5 of the office action mailed on 9/19/2007, is *withdrawn*.

In the response received on 12/26/2007, the Applicants note that the claim has been amended to remove recitation of "non-identical epitopes". The Applicants argue that neither Vannier nor Loosfelt teach a protein comprising epitope-containing segments comprising two or more identical epitopes, and

therefore do not teach the ubiquitin fusion proteins of the instant invention. The Applicants also argue that the ubiquitin fusion proteins of the instant invention were unknown in the art at the time of the invention, and it was not known that the present invention would be effective in the detection of antibodies since the fusion proteins of the instant invention are made at ubiquitin sites that are not typically used or found natively.

These arguments have been fully considered and are persuasive; accordingly, the rejection is withdrawn.

New Grounds of Rejection

Claim Rejections - 35 USC § 112, first paragraph – written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 86 is rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to a method of detecting specific antibodies in experimental or clinical samples, wherein said method comprises providing an ubiquitin fusion protein comprised of one or more epitope-containing segments comprising two or more identical epitopes. However, the claim does not require that the epitopes of the instant invention have any particular biological activity, or any particular structure, other than to be fused to ubiquitin. In the Applicants' response received on 12/27/2007, the Applicants define an epitope as the amino acid residues of a protein molecule which interact directly through noncovalent bonds with the amino acid residues of a particular antibody, and the average epitope probably involves about 15-20 contact amino acid residues, but only one or two (or 5-6 according to DeLisser) of these may be critical to the epitope's specificity. The Applicants also state that B-cell epitopes may be either linear or conformational in nature.

The specification describes ubiquitin fused to various epitopes of the HIV gp120 V3 loop, and also to epitopes of GnRH, but does not describe any other peptide or protein comprising *multiple identical* epitopes. There is no description of any naturally-occurring or artificial polypeptides, other than the

disclosed gp120- and GnRH-based peptides, comprising multiple, identical epitopes of 15-20 amino acids, or multiple, identical amino acid sequences which produce identical conformational shapes. Furthermore, although the specification describes the above-mentioned gp120- and GnRH-based peptides, there is no disclosure of these peptides having *multiple identical* epitopes, and even if these peptides do in fact comprise multiple identical epitopes, these examples by themselves are not sufficient to describe the entire genus of peptides having multiple identical epitopes. Thus, the specification has not adequately described the genus of polypeptides/peptides which comprise multiple identical epitopes in such a way as to convey to a person of ordinary skill in the art the nature or identity of such polypeptides, or that the Applicants were in possession of the claimed genus at the time of invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a requirement that the claimed peptides comprise ubiquitin fused to epitope-containing segments comprising multiple, identical epitopes. There is no identification of any peptide, other than the gp120- and GnRH-based peptides described in the specification, that comprises multiple identical epitopes, and there is no identification of any particular epitopes, other than gp120 or GnRH epitopes, which would assume a correct conformation when fused to ubiquitin so as to be sufficiently antigenic. Accordingly, in the absence of sufficient distinguishing characteristics, the specification does not provide adequate written description of the claimed genus.

Conclusion

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571)272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646